

## **REMARKS**

Claims 1 and 11 have been amended to incorporate the subject matter of claim 2, which has been canceled, without prejudice, and further to specify the sizes of the porous bodies. Claim 1 was further limited to water soluble porous bodies, and to specify that a water-insoluble material is incorporated into said lattice to be dispersed when the water-soluble porous body dissolves. The porous body is clarified to be a water-soluble lattice containing a water-insoluble “payload” material, as distinguished from the cited art. Support for this subject matter may be found throughout the Specification.

Claim 8 has been amended by incorporating the subject matter of claim 9, which has been canceled, without prejudice.

Claim 22 has been canceled, without prejudice.

Care has been taken not to introduce any new matter.

## **The Present Invention**

The present invention relates to water soluble or dispersible porous bodies and to methods of producing such porous bodies.

### **Double Patenting**

Claims 1-22 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/587,734 and Claims 1-3, 5, 8-14, 16 and 18-20 were provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-3, 5-10 and 12-18 of copending Application No. 10/587,722. While respectfully traversing due to claim differences, especially in view of the present amendments, applicants submit a terminal disclaimer in the effort to expedite the prosecution of the present case to issuance without delay.

### ***Claim Rejections – 35 USC § 102***

Claims 1, 3-4, 11, 13 and 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Fujimoto, et al., (Patent Abstracts of Japan, Publication no. 01011141).

While Applicants respectfully traverse, especially in view of the lack of proper standard stated for inherency, this rejection has been obviated by including the subject matter of claim 2 in independent claims 1 and 11.

### ***Claims Are Not Obvious under 35 USC § 103***

Claims 1-10 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wu, et al., (US 5,025,004) and further in view of Kitagawa (US 6,048,908). According to the Office Action, as to claims 1 and 2, Wu, et al., teach a process for preparing solid, powdered, polymeric compositions (column 3, lines 6-8), said powdered compositions of which are readily dispersible in water (column 3, lines 18-22) comprising at least one polymeric, water soluble or water dispersible, nonionic emulsifier (column 3, lines 51-53) in an amount of from 0.5 to 70% (column 4, lines 17-18) and additionally comprising an additive in an amount from 10 to 25% weight which can include surfactants such as Tween 80 (column 8, lines 51-60). ; The powders taught by Wu, et al., have a particle size in the range of from 10  $\mu\text{m}$  to 30  $\mu\text{m}$  (meaning the particles are not spheres with a diameter of from 0.2 to 0.5 mm) (column 8, lines 37-39).

The Office Action acknowledges that Wu, et al., fail to explicitly teach that the polymeric compositions have an intrusion volume as measure by mercury porosimetry of at least about 3 mL/g.

However, according to the Office Action, since the same composition that is disclosed in claim 1 is taught in Wu, et al., one of ordinary skill in the art would expect that the composition of Wu, et al., would have the same properties as the composition disclosed in claim 1, and would therefore have the specified intrusion volume.

Further, the Office Action acknowledges that Wu, et al., do not specify that the powdered polymeric materials are porous.

However, Kitagawa is cited for porous hydrophilic microbeads, produced using a formulation which comprises from 0.5 to 50% by weight monomer (column 7, lines 53-56) and 1 to 30% weight of surfactant (column 9, lines 4-8), said microbeads of which are used for drug carriers (column 15, lines 3-7). According to the Office Action, one of ordinary skill in the art would expect that if the powdered polymeric compositions of Wu, et al., were porous, it would aid the medicaments for which it is used (column 3, lines 5-10) in distribution throughout the body (Kitagawa (US 6,048,908), columns 15, lines 4-5).

Further according to the Office Action, as to claims 3-4, Wu, et al., teach the process for preparing the composition as applied to claim 1, wherein the polymeric materials can comprise cellulose acetate (column 6, lines 11).; As to claims 5 and 7, Wu, et al., teach the process for preparing a composition as applied to claim 1 in which the surfactant is nonionic Tween 80, polyethylene glycol sorbitan monoleate (column 8, line 60).

The Office Action acknowledges, as to claim 6, Wu, et al., do not specify that the surfactant used in the invention is solid at ambient temperature.

However, Kitagawa is cited for the use of distearate as a surfactant which is solid at room temperature (column 8, lines 52-54).

Further according to the Office Action, as to claims 8-9 and 22, Wu, et al., teach the process for preparing the composition as applied to claim 1, further comprising at least one water insoluble polymer (column 8, lines 25-26) and a water soluble polymers (column 8, lines 56-59).; Wu, et al., further teach dispersing the powdered, polymeric composition into an aqueous solution (column 8, lines 45-46).; As to claim 10, Wu, et al., teach the process for preparing the composition as applied to claim 1, and further teach that said composition can be used to prepare a cosmetic composition, said cosmetic composition of which contains at least one active ingredient such as a UV absorber (column 9, lines 45-53).

Claims 11-22 were rejected under 35 U.S.C. 103(a) as being unpatentable over Wu, et al., (US 5,025,004) and further in view of Kitagawa (US 6,048,908) and Monforte, et al., (US 3,551,533). According to the Office Action, as to claim 11-12, Wu, et al., teach preparing solid, powdered, polymeric compositions (column 3, lines 6-8), said powdered compositions of which are readily dispersible in water (column 3, lines 18-22) comprising at least one polymeric, water soluble or water dispersible, nonionic emulsifier (column 3, lines 51-53) in an amount of from 0.5 to 70% (column 4, lines 17-18) and additionally comprising an additive in an amount from 10 to 25% weight which can include surfactants such as Tween 80 (column 8, lines 51-60). Wu, et al., further teach that the composition contains at least one water-in-oil emulsifier (column 3, lines 50-68).; Wu, et al., further disclose that the composition comprises an organic solvent (liquid medium) (column 3, lines 44-48). ; Wu, et al., teach passing the polymer solution-in-water emulsion through a particle size reduction means such that the polymer is in the form of droplets having an average size in the range of about 0.1 to

0.8  $\mu\text{m}$ , followed by removing the organic solvent to form aqueous dispersion, and drying the dispersion to form the water dispersible powder (column 4, lines 45-62). Wu, et al., teach drying the particles by freeze drying (column 8, lines 17-20).

The Office Action acknowledges that neither Wu, et al., nor Kitagawa teach the steps of freeze drying the porous materials.

According to the Office Action, one of ordinary skill in the art would recognize that freeze drying employs a fluid freezing medium used to rapidly freeze a composition and further employs drying by sublimation.; For example, Monforte, et al., teaches breaking up a solute material into fine droplets, rapidly freezing the droplets to prevent coalescence (freeze-drying) and removal of the solvent by sublimation (column 1, lines 46-54). ; The dried droplets of Monforte, et al., are porous (column 1, lines 57).

Further according to the Office Action, as to claim 13, Wu, et al., teach the process for preparing the composition as applied to claim 1, wherein the polymeric material can comprise cellulose acetate (column 6, lines 11).; As to claims 14 and 16-17, Wu, et al., teach the process for preparing a composition as applied to claim 1 in which the surfactant is nonionic Tween 80, polyethylene glycol sorbitan monooleate (column 8, line 60).

The Office Action acknowledges, as to claim 15, Wu, et al., do not specify that the surfactant used in the invention is solid at ambient temperature.

However, Kitagawa is cited for the use of distearate as a surfactant which is solid at room temperature (column 8, lines 52-54).

Further according to the Office Action, as to claims 18-19, Wu, et al., and Kitagawa teach the polymeric compositions as applied to claim 11. ; Kitagawa teaches porous hydrophilic microbeads, produced using a formulation which comprises from 0.5

to 50% by weight monomer (column 7, lines 53-56) and 1 to 30% weight of surfactant (column 9, lines 4-8), said microbeads of which are used for drug carriers (column 15, lines 3-7).; Kitagawa further teaches that the discontinuous oil phase can be about 10%, about 20%, about 30%, about 40%, about 50% or about 60%, and as high as 99% of the emulsion (column 11, lines 38-50).; As to claim 20, Wu, et al., and Kitagawa teach the polymeric compositions as applied to claim 11 which further comprises solvents including alicyclic hydrocarbons, ethers, and esters (column 5, lines 31-43).; As to claims 21-22, Wu, et al., teach the composition as applied to claim 11 and further teach dispersing the powdered, polymeric composition into an aqueous solution (column 8, lines 45-46).; It would have been obvious for one of ordinary skill in the art to combine Wu, et al., and Kitagawa because both disclose compositions comprising acrylate polymers (Kitagawa, column 7, lines 27-28; Wu, et al., column 6, line 29) and surfactants (Kitagawa, column 8, lines 54; Wu, et al., column 8, line 60) to make hydrophilic, water dispersible products used in pharmaceuticals (Kitagawa, column 15, lines 4-6; Wu, et al., column 3, lines 6-9).

Applicants respectfully traverse. Reference is made to the claim amendments made herein and discussed above.

Wu are concerned with preparing polymeric compositions which are suitable for coating medicaments. See Abstract. Wu disclose bodies formed of a water-insoluble polymer, this is dispersible in water but not soluble. The bodies can be dispersed in water to form a "coating dope" that is used to coat other medicaments. Additives can be present (and these can include water soluble polymers - see column 8, line 56 ff), but these are only present at low levels. Given that Wu do not disclose the same materials, one of ordinary skill could not reach the conclusion that, as the bodies dissolve (which they do not), they would release the water-insoluble material incorporated into the lattice.

Kitagawa, discloses crosslinked particles of the polymerised "high internal phase" emulsion type. These are otherwise known as polyHIPE materials and are well known and used as "super-adsorbers" in all sorts of applications due to their high capacity for adsorbing and retaining liquids. If they dissolved, they would not be much good for this. Thus, like the previous case, the matrix is insoluble. As is shown in the examples of Kitagawa, the beads can adsorb large quantities of water without dissolving. Accordingly, one skilled in the art at the time the invention was made would not arrive at the present invention from a contemplation of Kitagawa, as this citation is concerned with water insoluble materials for use to adsorb fluids rather than any kind of delivery system for water soluble materials.

Monforte provide a general disclosure about freeze-drying an atomised liquid. The problem of getting insoluble materials into the particles is discussed (column 1, at line 20). However, the use of emulsions is not suggested, and so directly incorporating materials which are not water soluble is not disclosed. There is also no disclosure of the use of polymers and surfactants as in the present case.

The cited references either alone or in combination fail to render the present claims obvious.



### **CONCLUSION**

Reconsideration of the rejection is respectfully requested in view of the above claim amendments and remarks.

It is respectfully requested that the application be allowed to issue.

If a telephone conversation would be of assistance, Applicant's undersigned attorney invites the Examiner to telephone at the number provided.

Respectfully submitted,

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